

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA**

TERRE HAMMONDS,)	
)	
Plaintiff,)	
vs.)	NO. CIV-11-0663-HE
)	
BOSTON SCIENTIFIC, INC.,)	
)	
Defendant.)	

ORDER

Presently before the court is defendant Boston Scientific, Inc.’s (“Boston”) motion to dismiss plaintiff’s amended complaint. The amended complaint alleges various claims¹ stemming from a Pinnacle Pelvic Floor device (the “Pinnacle”) manufactured by Boston. According to plaintiff’s amended complaint, the Pinnacle is a type of surgical mesh used in connection with certain types of surgeries which was implanted in plaintiff during a surgical operation in August 2008. The court previously granted Boston’s motion to dismiss plaintiff’s original complaint and granted plaintiff leave to file an amended complaint. Plaintiff then filed the amended complaint to which defendant’s present motion is directed.

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss a claim when a party fails “to state a claim upon which relief can be granted.” When considering a Rule 12(b)(6) motion, all well-pleaded factual allegations in the complaint are accepted as true and those allegations, and any reasonable inferences that might be drawn from them, are

¹*Plaintiff’s complaint includes claims for negligence, strict liability, breach of express warranty, breach of implied warranties, fraudulent misrepresentation, fraudulent concealment, and violation of the Oklahoma Consumer Protection Act.*

construed in the light most favorable to the nonmoving party. Peterson v. Grisham, 594 F.3d 723, 727 (10th Cir. 2010). The question is whether the complaint contains “enough facts to state a claim to relief that is plausible on its face.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A plaintiff must “frame a ‘complaint with enough factual matter (taken as true) to suggest’ that he or she is entitled to relief.” Robbins v. Oklahoma, 519 F.3d 1242, 1247 (10th Cir. 2008) (quoting Twombly, 550 U.S. at 556). “[A] plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Twombly, 550 U.S. at 555.

With respect to the negligence and strict liability theories of products liability, the most significant modification in plaintiff’s amended complaint is the inclusion of ¶9, which provides:

The Pinnacle and the surgical mesh used to manufacture the Pinnacle have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to:

- a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.
- b. The mesh material harbors infections that adversely affect human tissues and patient health.
- c. The Pinnacle and the mesh migrate from the location of their implantation, adversely affecting tissues and patient health.
- d. The mesh material abrades tissues adversely affecting patient health.

- e. The Pinnacle and the mesh regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.
- f. Due to their various defects, the Pinnacle and the mesh regularly cause significant injury to patients such that the Pinnacle must be removed, resulting in additional surgery.
- g. The Pinnacle and the mesh become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to organs and tissues, adversely affecting patient health.

[Doc. #22]. The complaint further states that these defects created an unreasonable risk of certain specified injuries. *Id.* ¶ 10. It alleges Boston knew or should have known about these risks before the Pinnacle was implanted in the plaintiff but failed to take appropriate action. *See id.* ¶¶ 11, 15-17. The complaint then avers Boston “was negligent in failing to use reasonable care in designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling the Pinnacle . . .,” *id.* ¶ 20; and, that “the Pinnacle was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.” *Id.* ¶ 26.

Even with the addition of this list of potential defects, the averments are still conclusory and give little, if any, indication of what happened to plaintiff. Noticeably absent from the amended complaint is any statement of how *this specific* Pinnacle device failed or otherwise caused injury to the plaintiff. After reading the amended complaint, the defendant would still be understandably uncertain as to what plaintiff claims it did or failed to do.

The court is mindful of the difficulty in pleading a claim for relief based on an allegedly defective medical device. There is often a significant imbalance of information between the plaintiff and defendant. An injured plaintiff may have no way to know the precise defect in a medical device until after he or she has conducted discovery. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 558-60 (7th Cir. 2010). However, a complaint should include sufficient factual detail to put the defendant on notice of the nature of the plaintiff's injury and the circumstances surrounding it. The amended complaint does not do so.


With respect to plaintiff's remaining claims, her amended complaint still fails to identify what warranties and misrepresentations were made. It alleges that Boston made public and private statements it knew or should have known were false. [Doc. #22, ¶¶ 13, 14, 36, 45, 53, 64,75]. These conclusory allegations fail to identify any particular representation and, to the extent some fraudulent misrepresentation is alleged, fail to satisfy the particularity requirements of Rule 9(b). *See United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726-27 (10th Cir. 2006) (noting that Rule 9(b) requires a plaintiff to set out the "who, what, when, where and how of the alleged fraud.") (citations omitted). Plaintiff's argument in her response to the present motion that some of these statements were made on defendant's website "for the entire world to see" does not cure the complaint's deficiencies.

The amended complaint remains the type of bare elements recitation which resulted in the dismissal of the original complaint. Accordingly, defendant's motion to dismiss plaintiff's amended complaint [Doc. #23] is **GRANTED**. Plaintiff is again granted leave to

amend her complaint to remedy the indicated defects, if she can, **within twenty-one (21)**
days of entry of this order.

IT IS SO ORDERED.

Dated this 19th day of October, 2011.



JOE HEATON
UNITED STATES DISTRICT JUDGE